

Lipoic Acid Capsules

Alpha Lipoic Acid Capsules contain not less than 90.0 percent and not more than 115.0 percent of the labeled amount of $C_8H_{14}O_2S_2$.

Packaging and storage— Preserve in well-closed containers.

Identification— The retention time of the major peak in the chromatogram of the Test solution corresponds to that in the chromatogram of the Standard solution, as obtained in the test for Content of alpha lipoic acid.

[Disintegration and dissolution](#) [2040](#) —

Medium: water; 900 mL.

Apparatus 1 (for hard gelatin capsules): 100 rpm.

Apparatus 2 (for soft gelatin capsules): 75 rpm.

Time: 60 minutes.

Determine the amount of $C_8H_{14}O_2S_2$ dissolved by employing the following method.

Mobile phase and Chromatographic system— Proceed as directed in the test for Content of alpha lipoic acid.

Standard solution— Dissolve an accurately weighed quantity of [USP Alpha Lipoic Acid RS](#) in a mixture of acetonitrile and water (1:1) to obtain a solution having a known concentration of 1 mg per mL. Transfer 1 mL of this solution to a 50-mL volumetric flask, dilute with water to volume, and mix to obtain a solution having a known concentration of about 0.02 mg per mL.

Test solution— Withdraw a portion of the solution under test, and filter, discarding the first portion of the filtrate. Transfer an accurately measured aliquot to a volumetric flask, and dilute with water to volume to obtain a solution having an expected concentration of about 0.02 mg of alpha lipoic acid per mL.

Procedure— Separately inject equal volumes (about 50 μ L) of the Standard solution and the Test solution into the chromatograph, record the chromatograms, and measure the peak areas.

Determine the amount of $C_8H_{14}O_2S_2$ dissolved by the formula:

$$900CD(r_U / r_S)$$

in which C is the concentration of [USP Alpha Lipoic Acid RS](#) in the Standard solution; D is the dilution factor of the Test solution; and rU and rS are the peak areas of alpha lipoic acid obtained from the Test solution and the Standard solution, respectively.

Tolerances— Not less than 70% of the labeled amount of C₈H₁₄O₂S₂ is dissolved in 60 minutes.

[Weight variation](#) [2091](#) : meet the requirements.

Content of alpha lipoic acid—

Mobile phase— Prepare a filtered and degassed mixture of 0.025 M phosphoric acid and acetonitrile (62:38).

Standard solution— Dissolve an accurately weighed quantity of [USP Alpha Lipoic Acid RS](#) in acetonitrile and water (1:1), and dilute quantitatively, and stepwise if necessary, with acetonitrile and water (1:1) to obtain a solution having a known concentration of 0.05 mg per mL.

Test solution 1 (for hard gelatin capsules)— Empty and mix thoroughly the contents of not fewer than 20 Capsules. Transfer an accurately weighed portion of the powder, equivalent to about 100 mg of alpha lipoic acid, to a suitable container, add about 70 mL of a mixture of acetonitrile and water (1:1), and shake for 45 minutes by mechanical means. Transfer to a 100-mL volumetric flask, dilute with the mixture of acetonitrile and water (1:1) to volume, mix, and filter a portion of this preparation, discarding the first 5 mL of the filtrate. Transfer 5.0 mL of the remaining filtrate to a 100-mL volumetric flask, dilute with acetonitrile and water (1:1) to volume, and mix.

Test solution 2 (for soft gelatin capsules)— Using a suitable cutting instrument, open an accurately counted number of Capsules equivalent to about 500 mg of alpha lipoic acid. Transfer the contents and the shells to a suitable container with stopper, add 500.0 mL of a mixture of acetonitrile and water (1:1), and shake for 45 minutes by mechanical means. Filter a portion of this preparation, discarding the first 5 mL of the filtrate. Transfer 5.0 mL of the remaining filtrate to a 100-mL volumetric flask, dilute with acetonitrile and water (1:1) to volume, and mix.

Chromatographic system— The liquid chromatograph is equipped with a 220-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1.5 mL per minute.

Chromatograph the Standard preparation, and record the peak responses as directed for Procedure: the tailing factor for alpha lipoic acid is not more than 1.2; the efficiency of the column is not less

than 1300 theoretical plates; and the relative standard deviation for replicate injections is not more than 1.0%.

Procedure— Separately inject equal volumes (about 20 μL) of the Standard solution and the appropriate Test solution into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of alpha lipoic acid in the portion of hard gel Capsules taken by the formula:

$$2000C(r_U / r_S)$$

in which C is the concentration, in mg per mL, of [USP Alpha Lipoic Acid RS](#) in the Standard solution; and r_U and r_S are the peak responses of alpha lipoic acid obtained from Test solution 1 and the Standard solution, respectively. Calculate the quantity, in mg, of alpha lipoic acid in each soft gel Capsule taken by the formula:

$$10,000(C/N)(r_U / r_S)$$

in which C is the concentration, in mg per mL, of [USP Alpha Lipoic Acid RS](#) in the Standard solution; N is the number of Capsules taken; and r_U and r_S are the peak responses of alpha lipoic acid obtained from Test solution 2 and the Standard solution, respectively.